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K000813

XIV. SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
FLEXAM NITRILE T AMBI EXAMINATION GLOVES

Applicant/Sponsor: Allegiance Healthcare Sdn. Bhd.
1500 Waukegan Road
McGaw Park, IL 60085

Regulatory Affairs Contact: Erica Sethi
Allegiance Healthcare Corporation
1500 Waukegan Road, Bldg. WM
McGaw Park, IL 60085

Telephone: (847) 785-3337

Date Summary Prepared: February 1, 2000

Product Trade Name: Flexam Nitrile T Ambi Examination Gloves

Common Name: Examination Glove

Classification: Patient Examination Glove

Predicate Devices: Nitrile Powder-Free Examination Gloves, Sage Products Inc.

Description: Flexam Nitrile T Ambi Examination Gloves are formulated using nitrile and offered non-sterile.

Intended Use: These examination gloves are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner. In addition, these gloves are worn to protect the wearer against exposure to chemotherapeutic agents.

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Substantial Equivalence: Flexam Nitrile T Ambi Examination Gloves are substantially equivalent to Nitrile Powder-Free Examination Gloves manufactured by Sage Products Inc. in that they provide the following characteristics:

- same intended use
- same sizes
- both made of nitrile
- both offered non-sterile, beaded and powder-free
- both protect the wearer against exposure to chemotherapeutic agents

Summary of Testing:

Test	Result
Intracutaneous Reactivity	Gloves show no reactivity.
Guinea Pig Maximization	Gloves do not display any potential for irritation.
Tensile Strength	Gloves meet or exceed requirements per ASTM D3578-99.
Barrier Defects	Gloves meet or exceed requirements per 21 CFR§800.20 and ASTM D3578-99.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2000

Ms. Erica Sethi
Allegiance Healthcare Corporation
1500 Waukegan Road
William Merz Building
McGaw Park, Illinois 60085

Re: K000813
Trade Name: Flexam Nitrile T Ambi Examination Gloves with Chemo Claim
Regulatory Class: I
Product Code: LZA/LZC
Dated: May 1, 2000
Received: May 15, 2000

Dear Ms. Sethi

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2460

Applicant: Allegiance Healthcare Corporation

510(k) Number: K000813

Device Name: Flexam Nitrile T Ambi Examination Gloves

Indications For Use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. In addition, these gloves are worn to protect the wearer against exposure to chemotherapeutic agents.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000813